

Applicant or Patentee: Philip O. Livingston and Friedhelm Helling Attorney's  
Serial or Patent No.: 08/475,784 Docket No: 43016-C JPW/AKC  
Filed or Issued: June 7, 1995  
Title of Invention or Patent: GANGLIOSIDE-KLH CONJUGATE VACCINE PLUS QS-21



VERIFIED STATEMENT (DECLARATION) CLAIMING  
SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f)  
AND §1.27(d) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

Name of Organization: Sloan-Kettering Institute for Cancer Research

Address of Organization: 1275 York Avenue  
New York, New York 10021

TYPE OF ORGANIZATION:

- UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION  
TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and  
501(c)(3)  
 NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED  
STATES OF AMERICA

NAME OF STATE:

CITATION OF STATUTE:

WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C.  
§§501(a) and 501(c)(3) IF LOCATED IN THE UNITED STATES OF AMERICA

WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE  
OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA

NAME OF STATE:

CITATION OF STATUTE:

I hereby declare that the nonprofit organization identified above qualifies as a  
nonprofit organization as defined in 37 C.F.R. §1.9(e)\* for purposes of paying  
reduced fees under 35 U.S.C. §41(a) and 41(b), with regard to the invention entitled  
GANGLIOSIDE-KLH CONJUGATE VACCINE PLUS QS-21

by inventor(s) Philip O. Livingston and Friedhelm Helling

described in:

- the specification filed herewith  
 application serial no 08/475,784 filed June 7, 1995  
 patent no. issued

I hereby declare that rights under contract or law have been conveyed to and remain  
with the nonprofit organization with regard to the above identified invention.

If the rights held by the nonprofit organization are not exclusive each individual,  
concern, or organization known to have rights to the invention is listed below and  
no rights to the invention are held by any person, other than the inventor, who could  
not qualify as a small business concern under 37 C.F.R. §1.9(d)\* or a nonprofit  
organization under 37 C.F.R. 1.9(e)\*

\*NOTE: Separate verified statements are required from each person, concern, or  
organization having rights to the invention averring to their status as small  
entities. 37 C.F.R. §1.27.

Name: Progenics Pharmaceuticals, Inc.

Address: Old Saw Mill River Road, Tarrytown, New York 10591

Individual  Small Business Concern  Nonprofit Organization

37 C.F.R. §§1.9(d), 1.9(e)

(d) A small business concern as used in this chapter means any business concern as defined by the Small Business Administration in 13 C.F.R. §121.3-18, published on September 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:

§121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.

(a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.

(b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that determination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination file to the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and Trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.

(e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of this section if it were located in this country.

Small Entity/Nonprofit  
Page -2-

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)\*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: James S. Quirk  
Title In Organization: Senior Vice President, Research Resources Management  
Address: 1275 York Avenue  
New York, New York 10021  
Signature: James S. Quirk  
Date Of Signature: 8/2/95

37 C.F.R. §1.28(b)

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to §1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to §1.34(a) of this part.

Applicant or Patentee: Philip O. Livingston and Friedhelm Helling Docket # 43016-C JPW/AKC  
Serial or Patent No.: \_\_\_\_\_  
Filed or Issued: \_\_\_\_\_



Title of Invention or Patent: GANGLIOSIDE-KLH CONJUGATE VACCINE PLUS QS-21

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY H.B.  
STATES UNDER 37 C.F.R. §1.9(f) AND §1.27(c) - SMALL BUSINESS CONCERN

I hereby declare that I am:

- the owner of the small business concern identified below.
- an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Concern: Progenics Pharmaceuticals, Inc.  
Address of Concern: Old Saw Mill River Road  
Tarrytown, New York 10591

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 37 C.F.R. §121.3-18, reproduced in 37 C.F.R. §1.9(d), for purposes of paying reduced fees under 35 U.S.C. §41(a) and §41(b), in that the number of employees of the concern, including those of its affiliates, does not exceed five hundred (500) persons. For purposes of this verified statement, the number of employees of the business concern is the average number, over the previous fiscal year, of the persons employed by the business concern on a full-time, part-time, or temporary basis during each pay period of the fiscal year, and concerns are affiliates of each other when, either directly or indirectly, one concern controls or has power to control the other, or a third party or parties controls or has power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled

GANGLIOSIDE-KLH CONJUGATE VACCINE PLUS QS-21  
described in:

the specification filed herewith  
 application serial no. \_\_\_\_\_ filed June 7, 1995  
 patent no. \_\_\_\_\_ issued \_\_\_\_\_

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. §1.9(c)\*, any concern which could not qualify as a small business concern under 37 C.F.R. §1.9(d)\* or as a nonprofit organization under 37 C.F.R. §1.9(e)\*.

Name: Sloan-Kettering Institute for Cancer Research  
Address: 1275 York Avenue, New York, New York 10021

Individual     Small Business Concern     Nonprofit Organization

\*NOTE: Separate verified statements are required for each named person, concern, or organization having rights to the invention averring to their status as small entities. 37 C.F.R. §1.27.

\*See Reverse

(c) An independent inventor as used in this chapter means any inventor who (1) has not assigned, granted, conveyed, or licensed, and (2) is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not likely be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.

(d) A small business concern as used in this chapter means any business concern as defined by the Small Business Administration in 13 C.F.R. §121.3-18, published on September 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:

121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.

(a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.

(b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that determination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination file to the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.

(e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of this section if it were located in this country.

Small Entity/Small Business Concern  
Page -2-

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate.

37 C.F.R. §1.28(b)\*

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Paul J. Madden

Title In Organization: Chairman, Scientific Director & CEO

Address: Old Saw Mill River Road  
Tarrytown, New York 10591

Signature: Paul J. Madden

Date of Signature: May 3, 1995

\*See Reverse

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to §1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to §1.34(a) of this part.